DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 19, 2014

TurboSEAL, L.P.
% Ian Marsden
Regulatory Affairs Manager
Dohmen Life Science Services, LLC
11925 W I-70 Frontage Road North, Suite 900
Wheat Ridge, CO 80033

Re: K142483
Trade/Device Name: TurboSEAL™ Nasogastric Aspiration Tube (NGAT)
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: BSS, FEG
Dated: December 5, 2014
Received: December 9, 2014

Dear Ian Marsden,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K142483

Device Name
TurboSEAL™ Nasogastric Aspiration Tube (NGAT)

Indications for Use *(Describe)*
The TurboSEAL™ Nasogastric Aspiration Tube (NGAT) is intended for gastric decompression, gastric lavage and the administration of nutritional supplements through the distal tube port. It is also indicated for the aspiration of small quantities of refluxed gastric fluid from the distal esophageal aspiration areas.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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SECTION 7: 510(K) SUMMARY

Introduction:

This document contains the 510(k) Summary for the TurboSEAL™ Nasogastric Aspiration Tube (NGAT). The content of this summary is based on the requirements set forth in 21 CFR 807.92(c).

Applicant / Manufacturer Name and Address:

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Date Prepared: December 16, 2014

Device Name: TurboSEAL™ Nasogastric Aspiration Tube (NGAT), 1U-NGAT-01
TurboSEAL™ NGAT Holder,1-NGAT-H-01

Classification: Class II

Classification Name: Gastrointestinal Tube and Accessories

Regulation Number: 21 CFR 870.5980

Product Code: BSS, FEG

Predicate Devices:

The TurboSEAL™ NGAT is claimed to be substantially equivalent to the following legally marketed predicate device:

- Moss Tubes, Inc. Nasal Tube – Mark IV (K984629)
- Davol® Nasogastric Sump Tube with PreVent™ Anti-Reflux Filter, Davol Inc. (a Bard Company) (K960176)

Performance Standards:

No mandatory performance standards are established for this device.

The design of this device claims conformance to the following voluntary recognized consensus standards:

- BS/EN 1615:2000 - Enteral feeding catheters and enteral giving sets for single use and their connectors. Design and testing
- BS/EN 1618: 1997 - Catheters other than intravascular catheters. Test methods for common properties
- ANSI/AAMI/ISO 10993-1:2009/(R) 2013 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 11137-1:2006 - Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ANSI/AAMI/ISO 11137-2:2013 - Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose
- ASTM F2096:2011 - Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ASTM F88/F88M:2009 - Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1980:2007/(R)2011 - Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ISO 11607-1:2006 - Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ASTM D4169:2009 - Standard Practice for Performance Testing of Shipping Containers and Systems
- ISTA 2A:2009 – Partial Simulation Performance Tests, Packaged Products 150lb (68kg) or less

Device Description:

The TurboSEAL™ Nasogastric Aspiration Tube (NGAT) is a typical Nasogastric Tube (NGT) allowing for enteral feeding, gastric decompression and gastric lavage. Connection of the device to standard hospital suction enables the application of suction to two separate locations (the Distal and Proximal Aspiration Areas) located at the distal end of the device. Aspiration at these sites allows for the removal of gastric fluid that has entered the esophagus. Aspiration is limited to one aspiration site at a time, for a maximum duration of 5 hours at each site.

Intended Use, Indications for Use, Contraindications:

The TurboSEAL™ Nasogastric Aspiration Tube (NGAT) is intended for gastric decompression, gastric lavage and the administration of nutritional supplements through the distal tube port. It is also indicated for the aspiration of small quantities of refluxed gastric fluid from the distal esophageal aspiration areas.

The TurboSEAL™ NGAT is contraindicated for pregnant women, pediatric, and neonatal use.

Comparison of Indications for Use / Intended Use:

- Intended Use Comparison
  - The TurboSEAL™ NGAT and the predicate Davol® Nasogastric Sump Tube have similar intended uses. Both devices are intended for gastric decompression, gastric lavage, and the administration of nutritional supplements.
  - The TurboSEAL™ NGAT and the predicate Moss Mark IV Nasal Tube have similar intended uses. Both devices are intended for gastric decompression, administration of nutritional supplements, and gastric fluid aspiration.
- Indications for Use Comparison
  - The TurboSEAL™ NGAT and the predicate Davol® Nasogastric Sump Tube have similar indications for use. Both devices are indicated for gastric decompression, gastric lavage, and the administration of nutritional supplements.
  - The TurboSEAL™ NGAT and the predicate Moss Mark IV Nasal Tube have similar indications for use. Both devices are indicated for gastric decompression, enteral feeding (ie administration of nutritional supplements), and gastric fluid aspiration. Although the cleared indications for use for the Moss Mark IV Nasal Tube do not specifically state that the device is indicated for gastric fluid aspiration; the cleared instructions for use for the product specifically point to a number of aspiration areas on the device diagram. The aspiration areas are described as the "Esophageal [Aspiration] Orifices," "Gastric Aspiration Orifices," and "Duodenal Aspiration Orifices." Therefore, the Moss Mark IV Nasal Tube is also indicated for gastric fluid aspiration within the Instructions for Use cleared for the device.
  - The TurboSEAL™ NGAT is substantially equivalent to the indications for use of both predicate devices. The TurboSEAL™ NGAT has no additional indications for use beyond those of the predicate devices.

Comparison of Technological Characteristics:

The TurboSEAL™ NGAT has similar technological characteristics as compared to its identified predicate devices. All are multilumen nasogastric tubes that allow of the bidirectional movement of fluids in and out of the gastrointestinal (GI) tract.

- Gastric Decompression
  - Gastric decompression involves the removal of fluids and/or gas from the stomach to relieve excess gastric pressure. Gastric decompression is indicated by all three devices, and is achieved by using a lumen within the tube to vent excess pressure.

- Gastric Lavage
  - Gastric lavage is the process of introducing and subsequently removing fluids from the stomach to cleanse the contents of the stomach. Both the TurboSEAL™ NGAT and the Davol® Nasogastric Sump Tube are indicated for gastric lavage.

- Administration of Nutritional Supplements
    - All three devices are indicated for the administration of nutrition. Nutrition is administered through the use of valves and polymeric tubing providing a direct fluid path between the nutritional supplement source (eg feeding bag or feeding pump) and the GI tract of the patient.

- Gastric Fluid Aspiration
    - Gastric fluid aspiration is the process of removing air and/or fluid from the GI tract using a negative pressure source. Both the TurboSEAL™ NGAT and Moss Mark IV Nasal Tube are indicated for gastric fluid aspiration. Gastric fluid aspiration is achieved in both devices by applying negative pressure to the tube, causing the aspiration of fluid at various aspiration areas (ie aspiration orifices) along the length of the tube. The Moss Mark IV Nasal Tube contains esophageal, gastric, and duodenal aspiration areas. The TurboSEAL™ NGAT has nearly identical esophageal aspiration areas, and does not contain gastric or duodenal aspiration areas.

Summary of Performance Testing:

TurboSEAL, L.P. has performed extensive verification and validation testing to demonstrate the substantial equivalence of the TurboSEAL™ NGAT to the Davol® Nasogastric Sump Tube and the Moss Mark IV Nasal Tube. The TurboSEAL™ NGAT has been subjected to safety, performance, verification and validation testing to ensure that the device meets all of its functional requirements and intended uses. Testing has been performed to ensure that the device complies with all applicable industry and safety standards. The following list summarizes the testing performed on the TurboSEAL™ NGAT:

- Biocompatibility
- Sterilization
- Packaging
- Shelf Life
- Dimensional Inspection
- Liquid Leakage Testing
- Visual Inspection
- Tensile Strength Testing
- Simulated Use
- Gastric Fluid Compatibility
- Porcine Animal Study
    - Visual Examination (Gastroscopy)
    - Histology
    - Human Factors/Usability

As demonstrated by the results of the verification and validation testing, the minor differences in technological characteristics between the TurboSEAL™ NGAT and its predicate devices do not raise different questions of safety and effectiveness.

Conclusion:

The TurboSEAL™ NGAT is substantially equivalent with respect to the intended use/indications for use, technological characteristics, target user, patient population, and use environment to the following the legally marketed predicate devices:

- Moss Tubes, Inc. Nasal Tube – Mark IV, K984629
- Davol® Nasogastric Sump Tube with PreVent™ Anti-Reflux Filter, Davol Inc. (A Bard Company), K960176